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Frommer Lawrence & Haug  
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EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/06/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicati n No.

09/913,763

Applicant(s)

TAGG ET AL.

Examin r

Michael V. Meller

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 24-26 and 41-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 27-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

### Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the ground(s) that SEQ ID NOS: 1 (group I) and 3 (group II) are the same protein, that group III is the same except for one, two or three amino acids and that the protein and the DNA share a special technical feature. This is not found persuasive because as stated before the DNA (polynucleotide) encoding the protein does not share a special technical feature with the protein it encodes because it differs both in structure and function.

In light of applicant's arguments, the restriction requirement is hereby redrawn.

Group I is now claims 1-23, 27-40.

Group II is now claims 24 and 26.

Group III is now claim 25.

Group IV is now claims 41 and 43-45.

Group V is now claim 42.

Group VI is now claim 46.

Claim 46 does not share a special technical feature with the other claims since it is an isolated polypeptide encoded by the amino acid sequence of SEQ ID NO:1 not an antibacterial protein isolated from *Streptococcus salivarius*.

Therefore, claims 24-26 and 41-46 are withdrawn from further consideration by the examiner as being drawn to non-elected inventions.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Mr. Upton (or someone else) made alterations to the oath without initialing them.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-23 and 27-40 are rejected under 35 U.S.C. 101 because they recite products of nature and are therefore not patentable. Applicant can only receive a patent where a "hand of man" is involved. If applicant inserts, "isolated" or "purified" before the protein and "a biologically pure culture" before the microorganism, then this rejection would be overcome.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 and 27-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed strains *Streptococcus salivarius* DSM 13084 and DSM 13085 are required to practice the claimed invention and is not properly deposited under MPEP 2402-2411.05. See also 37 CFR 1.808 which regulates the "Furnishing of samples." See MPEP 2410. Note, a deposit made under the terms of the Budapest Treaty **does not, by itself**, meet all the requirements of 37 CFR 1.808. To meet the requirements of 37 CFR 1.808 when a deposit is made under the terms of the Budapest Treaty, applicant must also provide a statement to the effect that all restrictions on the

availability to the public of the deposited biological material will be irrevocably removed upon the granting of the patent. See MPEP 2410.01.

Further, applicant has not shown how one would know which amino acid in SEQ ID NO:3 to insert, delete or substitute. It is known in the art that changing the number or type of amino acid(s) in a protein fundamentally changes the structure and function of that protein. Since applicant has not provided any guidance on exactly what amino acid is changed, deleted, etc, it would be undue experimentation for one of ordinary skill in the art to determine which amino acid if changed or deleted would not change the fundamental characteristics of the protein defined by the claims of the instant invention.

Claims 1-23 and 27-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibacterial protein (SEQ ID NO: 3) isolated from *Streptococcus salivarius* DSM 13084 or DSM 13085 and its identifying characteristics or a biologically pure culture of *Streptococcus salivarius* DSM 13084 or DSM 13085 and its identifying characteristics, does not reasonably provide enablement for any and all antibacterial proteins and microorganisms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The invention is not properly enabled for any and all microorganisms and proteins as claimed. Applicant has only taught a specific microorganism (*Streptococcus salivarius* DSM 13084 or DSM 13085) and the protein (SEQ ID NO: 3) from it.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 and 27-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear since it is not evident if the protein is isolated from the microorganism or not. The claim must be written in definite terms.

It is also confusing when applicant defines the protein as having an N-terminal of SEQ ID NO:1 when in fact SEQ ID NO: 1 is part of SEQ ID NO: 3. It would be clearer if applicant simply stated that the protein has the amino acid sequence of SEQ ID NO: 3 and completely removed the SEQ ID NO: 1 identity.

Further, it is confusing how in claim 21 it further requires that a secondary antibacterial agent(s) is used and then in claim 22 it is claimed that the agent is BLIS which is inherently in the protein or microorganism as noted in applicant's specification at page 4, bottom.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15, 21-23 and 27-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Caufield et al.

Caufield teaches an antibacterial protein having 87 % amino acid identity to the claimed SEQ ID NO:3. The proteins of Caufield and the invention as claimed only differ by 4 amino acids. BLIS is inherently in the protein or microorganism since as applicants note at page 4 of their specification, the BLIS is inherently part of the protein or microorganism.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 13, 21-23 and 27-40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ross et al., Tagg, Sanders, Jr. et al., Matsushiro, or Kawai et al.

Each of the references teaches the claimed microorganism and protein isolated therefrom or in the very least it would have been obvious from the references that the

claimed invention was one and the same as the references. Some of the claimed characteristics are not specifically stated in the references but it would have been inherent to the references that they contain microorganisms or proteins as claimed or in the very least it would have obvious to isolated or biologically purify such proteins and microorganisms as claimed from the references since the references contain the same genus and species of microorganism as claimed, namely, *Streptococcus salivarius*.

BLIS is inherently in the protein or microorganism since as applicants note at page 4 of their specification, the BLIS is inherently part of the protein or microorganism.

Claims 1-23 and 27-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al., Tagg, Sanders, Jr. et al., Matsushiro, or Kawai et al.

Each of the references teaches the claimed microorganism and the protein isolated therefrom. The references do not teach all of the pharmaceutical formulations claimed and that a secondary antibacterial agent such as BLIS is specifically added to the therapeutic formulation.

It would have been obvious to use such formulations since such formulations are well known as is evident in Caufield. To use a food or a medicament is simply the choice of the artisan in an effort to optimize the results of the invention.

To add a secondary formulation containing BLIS is also obvious since it is inherently in the microorganism or protein since as applicants note at page 4 of their specification, the BLIS is inherently part of the protein or microorganism.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Michael V. Meller  
Examiner  
Art Unit 1651

MVM  
May 29, 2002